

## REMARKS

The specification has been amended to correct typographical errors and to reflect the drawing designations provided for in the formal drawings. The amendments to reflect the drawing designations have been made in order to conform to the current Patent Office regulations regarding formal drawings. A marked up version of the paragraphs in the specification amended herein, with deletions and additions indicated by brackets and underlining, respectively, is attached hereto in Exhibit A. No new matter has been introduced by the amendments to the specification.

Claims 132-264 were pending in this application. Claims 137, 139, 141, 143, 145, 147, 149, 151, 153, 156, 158, 160, 166, 167, 170, 172, 174, 179, 182, 184, 186, 190, 193, 195, 197, 202, 204, 206, 209, 214, 217, 219, 221, 225, 228, 230, 232, 236, 239, 241, 243, 244, 253 and 255 have been canceled without prejudice to Applicants' right to pursue the subject matter of the canceled claims in related applications. Claims 132, 140, 144, 148, 152, 159, 245-247, 254, and 256-264 have been amended to clarify what Applicants regard as the claimed invention. The amendments are fully supported by the specification of the instant application (see, *e.g.*, page 11, line 25 to page 12, line 31; page 13, line 35; page 51, line 1 to page 59, line 29; page 85, line 20 to page 102, line 5; page 104, line 18 to page 106, line 23; and page 121, line 22 to page 122, line 7 of the specification), and do not constitute new subject matter. A marked up version of the claims amended herein, with additions and deletions indicated by underlining and brackets, respectively, is attached hereto as Exhibit B. Claims 132-136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 155, 157, 159, 161-165, 168, 169, 171, 173, 175-178, 180, 181, 183, 185, 187, 188, 189, 191, 192, 194, 196, 198-201, 203, 205, 207, 208, 210-213, 215, 216, 218, 220, 222-224, 226, 227, 229, 231, 233-235, 237, 238, 240, 242, 245-252, 254, and 256-264 are, therefore, currently pending in the instant application. A copy of all of the claims, as amended, is attached hereto as Exhibit C.

Applicants respectfully request that the amendments and remarks made herein be entered and fully considered.

### **1. INFORMATION DISCLOSURE STATEMENT**

The Examiner acknowledges that an Information Disclosure Statement ("IDS") and revised PTO 1449 form were filed on January 25, 2001 in the United States Patent and Trademark Office ("USPTO"). However, the Examiner states that she was unable to find the

copies of references AC-AF, AU, AY, BA, BN, BX, CA and DD-DJ also filed on January 25, 2001 in the USPTO. Applicants respectfully assert that copies of references AC-AF, AU, AY, BA, BN, BX, CA and DD-DJ were, indeed, filed with the IDS and revised PTO 1449 form on January 25, 2001 in the USPTO using "Express Mail Post Office to Addressee" service under Express Mail Label No. 501 636 596 US. As evidence of the fact that copies of references AC-AF, AU, AY, BA, BN, BX, CA and DD-DJ were filed on January 25, 2001 in the USPTO and received by the USPTO, Applicants enclose herewith: (1) Exhibit D, a copy of Express Mail Label No. EL 501 636 596 US with the "date-in" January 25, 2001 and "time-in" 14:02; and (2) Exhibit E, a copy of the postcard, which listed on one side the items filed on January 25, 2001 and Express Mail Label No. EL 501 636 596 US, returned to Applicants' attorneys stamped received by the USPTO with the date of January 25, 2001. Accordingly, pursuant to 37 C.F.R. § 1.10 (a), Applicants did, indeed, file copies of references AC-AF, AU, AY, BA, BN, BX, CA and DD-DJ on January 25, 2001 in the USPTO.

The Examiner states that she was unable to find copies of references AA-AB, AG-AT, AV-AX, AZ, BB-BM, BO-BW, BY-BZ, CB-DC and DK in U.S. application Serial No. 09/345,068, filed June 30, 1999. As a result of a typographical error, the IDS filed on January 25, 2001 in the USPTO inadvertently recited U.S. application Serial No. 09/345,068 instead of U.S. application Serial No. 09/345,468. Copies of references AA-AB, AG-AT, AV-AX, AZ, BB-BM, BO-BW, BY-BZ, CB-DC and DK are available in U.S. application Serial No. 09/345,468, filed June 30, 1999.

In order to expedite the examination of the instant application, Applicants are filing herewith a Second Information Disclosure Statement, a second revised PTO 1449 form, and copies of references AA-DN listed on the revised PTO 1449 form. Applicants respectfully request that the Examiner review and consider references AA-DL listed on the revised PTO 1449 form enclosed herewith.

## **2. THE OBJECTIONS TO THE CLAIMS SHOULD BE WITHDRAWN**

The Examiner has advised that claims 155, 156, 161, 162, 175, 199, 200-208, 213, 214, and 233-241, if found allowable, will be objected to under 37 C.F.R. § 1.75 as being substantially duplicative of claims 152, 153, 142, 146, 163, 176-179, 181-184, 180, 185, 148, 149, and 222-230, respectively.

Applicants have canceled claims 149, 153, 156, 179, 182, 184, 202, 204, 206, 214, 225, 228, 230, 236, 239, and 241 without prejudice to Applicants' right to pursue the subject matter of the canceled claims in related applications. Applicants respectfully assert that claims 155, 161, 162, 175, 199, 200, 201, 203, 205, 207, 208, 213, 233, 234, 235, 237, 238 and 240 are not substantially duplicative of claims 152, 142, 146, 163, 176, 177, 178, 181, 183, 180, 185, 148, 222-224, 226, 227 and 229, respectively. For example, claim 155 recites a substantially purified antibody comprising a variable light ("VL") complementarity determining region ("CDR") 1 having an amino acid sequence of a VL CDR1 encoded by the cDNA insert of the plasmid deposited with the ATCC® as patent deposit No. PTA-2442, a VL CDR2 having having an amino acid sequence of a VL CDR2 encoded by the cDNA insert of the plasmid deposited with the ATCC® as patent deposit No. PTA-2442, and a VL CDR3 having an amino acid sequence of a VL CDR3 encoded by the cDNA insert of the plasmid deposited with the ATCC® as patent deposit No. PTA-2442. In contrast, claim 152 recites a substantially purified antibody comprising VL CDR1 having an amino acid sequence of a VL CDR1 encoded by the cDNA insert of the plasmid deposited with the ATCC® as patent deposit No. PTA-2442 and a VL CDR3 having an amino acid sequence of a VL CDR3 encoded by the cDNA insert of the plasmid deposited with the ATCC® as patent deposit No. PTA-2442. Thus, claims 155 and 152 recite antibodies having different, minimum requirements of CDRs. Therefore, contrary to the Examiner's contention, claims 155, 161, 162, 175, 199, 200, 201, 203, 205, 207, 208, 213, 233, 234, 235, 237, 238 and 240 are not substantially duplicative of claims 152, 142, 146, 163, 176, 177, 178, 181, 183, 180, 185, 148, 222-224, 226, 227 and 229, respectively.

Claims 137, 139, 141, 143, 145, 147, 149, 151, 153, 156, 158, 160, 167, 170, 172, 174, 179, 182, 184, 186, 190, 193, 195, 197, 202, 204, 206, 214, 217, 219, 221, 225, 232, 236, 243, 244, and 253 are objected to under 37 C.F.R. § 1.75 as being of improper dependent form for failing to further limit the subject matter of a previous claim. The Examiner contends that it is unclear how the recitation of a sequence such as SEQ ID NO.:66 which is inherent to what is encoded by deposit No. PTA-2442 further limits the base claim. As suggested by the Examiner, Applicants have canceled claims 137, 139, 141, 143, 145, 147, 149, 151, 153, 156, 158, 160, 167, 170, 172, 174, 179, 182, 184, 186, 190, 193, 195, 197, 202, 204, 206, 214, 217, 219, 221, 225, 232, 236, 243, 244, and 253 without prejudice to Applicants' right to pursue the subject matter of the canceled claims in related applications.

Accordingly, the cancellation of claims 137, 139, 141, 143, 145, 147, 149, 151, 153, 156, 158, 160, 167, 170, 172, 174, 179, 182, 184, 186, 190, 193, 195, 197, 202, 204, 206, 214, 217, 219, 221, 225, 232, 236, 243, 244, and 253 has rendered the objection to the claims moot. Therefore, the objection to claims 137, 139, 141, 143, 145, 147, 149, 151, 153, 156, 158, 160, 167, 170, 172, 174, 179, 182, 184, 186, 190, 193, 195, 197, 202, 204, 206, 214, 217, 219, 221, 225, 232, 236, 243, 244, and 253 should be withdrawn.

**3. THE REJECTIONS UNDER 35 U.S.C. § 112,  
FIRST PARAGRAPH, SHOULD BE WITHDRAWN**

**A. THERE IS WRITTEN DESCRIPTION  
SUPPORT FOR THE PENDING CLAIMS**

Claims 132-264 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. For the reasons detailed below, Applicants respectfully assert that the rejections under 35 U.S.C. § 112, first paragraph, for lack of written description support cannot stand and should be withdrawn.

Applicants have canceled claims 137, 139, 141, 143, 145, 147, 149, 151, 153, 156, 158, 160, 166, 167, 170, 172, 174, 179, 182, 184, 186, 190, 193, 195, 197, 202, 204, 206, 209, 214, 217, 219, 221, 225, 228, 230, 232, 236, 239, 241, 243, 244, 253 and 255 without prejudice to Applicants' right to pursue the subject matter of the canceled claims in related applications. Applicants have amended to claims 132, 140, 144, 148, 152, 159, 245-247, 254, and 256-264 to more particularly point and distinctly claim the subject matter of the invention. In particular, independent claims 132 and 254 have been amended to recite substantially purified antibodies that immunospecifically bind to a human TANGO 268 antigen. Claims 140, 144, 148, 152, 159, 245-247 and 256-264 have been amended so that they no longer depend from canceled claims.

With respect to claims 132-264, the Examiner contends that there is no written description support in the specification for the recited combinations and permutations of CDRs in the pending claims. Applicants respectfully assert that there is, indeed, written description support in the instant specification for the recited combinations and permutations of CDRs in the pending claims. Applicants direct the Examiner's attention to page 11, line 25 to page 12, line 31; page 13, line 35; page 85, line 20 to page 102, line 5; page 104, line 18

to page 106, line 23; page 114, lines 22-23; and page 121, line 22 to page 122, line 7 of the instant specification for support for the pending claims. In particular, support for claims 132-136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 155, 157, 159, 161-165, 168, 169, 171, 173, 175-178, 180, 181, 183, 185, 187, 188, 189, 191, 192, 194, 196, 198,-201, 203, 205, 207, 208, 210-213, 215, 216, 218, 220, 222-224, 226, 227, 229, 231, 233-235, 237, 238, 240, 242, 245-252, 254, and 256-264 can be found in the instant specification as, *e.g.*, detailed in Table 1.

The instant specification recites the antibodies that immunospecifically bind to a human TANGO 268 antigen, said antibodies comprising a VH domain having the amino acid sequence of one or more VH CDRs listed in Table 7 and/or a VL domain having the amino acid sequence of one or more of the VL domains listed in Table 7. Applicants respectfully point out that the CDR sequences recited in Table 7 for the scFv clone entitled A10 are encoded by the cDNA insert of the plasmid deposited with the ATCC® as patent deposit Number PTA-2442. Applicants respectfully assert that one of skill in the art would be able to ascertain the various combinations and permutations of the CDRs comprising the antibodies of the claimed invention based upon the written description in the specification of the instant application. Accordingly, Applicants respectfully assert that there is, indeed, written description support in the specification for the pending claims.

Table 1

Claim	Support in the Specification
132	page 95, line 33 to page 96, line 4
133	page 95, lines 33-34
134	page 95, lines 34-36
135	page 95, line 36 to page 96, line 4
136	page 97, lines 28-31
138	page 96, line 16-21
140	page 95, line 36 to page 96, line 4; page 99, lines 2-4
142	page 96, lines 16-23

144	page 95, line 36 to page 96, line 2; page 98, lines 26-32; page 99, lines 10-12
146	page 96, lines 16-19; page 96, lines 23-26
148	page 95, line 36 to page 96, line 2; page 98, lines 26-32; page 99, lines 18-20
150	page 97, lines 21-26
152	page 97, lines 21-24
154	page 97, lines 21-24; page 97, lines 32-35
155	page 97, lines 21-24; page 98, lines 5-9
157	page 97, lines 21-24; page 97, lines 26-28
159	page 97, lines 21-24; page 98, lines 2-5
161	page 96, lines 16-19; page 27-30
162	page 96, lines 16-19; page 96, lines 30-33
163	page 96, lines 16-19; page 96, line 36 to page 97, line 4
164	page 95, line 36 to page 96, line 2; page 98, lines 26-35
165	page 95, line 36 to page 96, line 2; page 98, lines 26-32; page 99, lines 2-5
168	page 95, line 36 to page 96, line 2; page 98, lines 26-32
169	page 95, line 36 to page 96, line 2; page 98, lines 26-32
171	page 95, line 36 to page 96, line 2; page 98, lines 26-32
173	page 95, line 36 to page 96, line 2; page 98, lines 26-32
175	page 96, lines 16-19; page 96, lines 33-36
176	page 95, line 36 to page 96, line 2; page 98, lines 26-32

177	page 95, line 36 to page 96, line 2; page 98, lines 26-32
178	page 95, line 36 to page 96, line 2; page 98, lines 26-32
180	page 95, line 36 to page 96, line 2; page 98, lines 26-32
181	page 95, line 36 to page 96, line 2; page 98, lines 26-32
183	page 95, line 36 to page 96, line 2; page 98, lines 26-32
185	page 95, line 36 to page 96, line 2; page 98, lines 26-32
187	page 95, line 36 to page 96, line 2; page 98, lines 26-32; page 99, lines 13-15
188	page 95, line 36 to page 96, line 2; page 98, lines 26-32; page 99, lines 15-18
191	page 95, line 36 to page 96, line 2; page 98, lines 26-32
192	page 95, line 36 to page 96, line 2; page 98, lines 26-32
194	page 95, line 36 to page 96, line 2; page 98, lines 26-32
196	page 95, line 36 to page 96, line 2; page 98, lines 26-32
198	page 95, line 36 to page 96, line 2; page 98, lines 26-32
199	page 95, line 36 to page 96, line 2; page 98, lines 26-32
200	page 95, line 36 to page 96, line 2; page 98, lines 26-32

201	page 95, line 36 to page 96, line 2; page 98, lines 26-32
203	page 95, line 36 to page 96, line 2; page 98, lines 26-32
205	page 95, line 36 to page 96, line 2; page 98, lines 26-32
207	page 95, line 36 to page 96, line 2; page 98, lines 26-32
208	page 95, line 36 to page 96, line 2; page 98, lines 26-32
210	page 95, line 36 to page 96, line 2; page 98, lines 26-32
211	page 95, line 36 to page 96, line 2; page 98, lines 26-32
212	page 95, line 36 to page 96, line 2; page 98, lines 26-32
213	page 95, line 36 to page 96, line 2; page 98, lines 26-32
215	page 95, line 36 to page 96, line 2; page 98, lines 26-32
216	page 95, line 36 to page 96, line 2; page 98, lines 26-32
218	page 95, line 36 to page 96, line 2; page 98, lines 26-32
220	page 95, line 36 to page 96, line 2; page 98, lines 26-32
222	page 95, line 36 to page 96, line 2; page 98, lines 26-32
223	page 95, line 36 to page 96, line 2; page 98, lines 26-32

224	page 95, line 36 to page 96, line 2; page 98, lines 26-32
226	page 95, line 36 to page 96, line 2; page 98, lines 26-32
227	page 95, line 36 to page 96, line 2; page 98, lines 26-32
229	page 95, line 36 to page 96, line 2; page 98, lines 26-32
231	page 95, line 36 to page 96, line 2; page 98, lines 26-32
233	page 95, line 36 to page 96, line 2; page 98, lines 26-32
234	page 95, line 36 to page 96, line 2; page 98, lines 26-32
235	page 95, line 36 to page 96, line 2; page 98, lines 26-32
236	page 95, line 36 to page 96, line 2; page 98, lines 26-32
238	page 95, line 36 to page 96, line 2; page 98, lines 26-32
240	page 95, line 36 to page 96, line 2; page 98, lines 26-32
242	page 95, line 36 to page 96, line 2; page 98, lines 26-32
245	page 95, line 33 to page 96, line 4
246	page 95, line 33 to page 96, line 4
247	page 95, line 33 to page 96, line 4
248	page 95, line 33 to page 96, line 4
249	page 95, line 33 to page 96, line 4
250	page 95, line 33 to page 96, line 4

251	page 95, line 33 to page 96, line 4
252	page 96, lines 4-6
254	page 13, line 35, page 114, lines 22-23, page 121, line 22 to page 122, line 7
256	page 87, lines 4-10; page 94, lines 29-31; page 94, lines 32-34
257	page 87, lines 4-10; page 87, lines 15-20
258	page 87, lines 4-10; page 87, lines 15-20
259	page 87, lines 4-10; page 87, lines 15-20
260	page 87, lines 4-10; page 87, lines 15-20
261	page 12, lines 21-22; page 105, lines 4-14
262	page 12, lines 21-25; page 105, lines 15-30
263	page 12, lines 27-31; page 106, lines 19-23
264	page 12, lines 26-27; page 106, lines 18-20

With respect to claims 132-230, 233-241, 244-251 and 256-264, the Examiner contends that there is no written description support for these claims since the sequence for all six CDRs are not defined. The Examiner contends that the structures of the antibodies recited in claims 132-230, 233-241, 244-251 and 256-264 are not conventional in the art and thus, one of skill in the art would not recognize from the disclosure that Applicants were possession of the antibodies recited in claims 132-230, 233-241, 244-251 and 256-264.

It is well established that the specification need not describe, and should preferably omit what is known in the art. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d. 1367, 231 UPSQ 81 (Fed. Cir. 1986); *In re Hayes Microcomputer Products, Inc. Patent Litigation*, 982 F.2d 1527, 25 USPQ2d 1241 (Fed. Cir. 1992); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991).

Applicants respectfully assert that the specification coupled with information well-known in the art as of the effective filing date of the instant application would reasonably convey to one of skill in the art that the Applicants were in possession of antibodies recited in claims 132-230, 233-241, 244-251 and 256-264. First, methods for generating antibodies comprising one defined CDR, wherein the antibodies immunospecifically bind to a particular

antigen were well-known in the art as of the effective filing date of the '118 application. See, e.g., Jirholt et al., 1998, Gene 215: 471-476 ("Jirholt"), Soderlind et al., 1999, Immunotechnology 4: 279-285 ("Soderlind"), and International Publication No. WO 98/32845 attached hereto as Exhibits G-I, respectively. Jirholt teaches methods for generating antibodies that differ in all three CDRs of the VH domain of an antibody (see, e.g., Figure 1 of Jirholt). Soderlind and International Publication No. WO 98/32845 teach methods of generating antibodies comprising one to six unknown CDRs. In particular, Soderlind and International Publication No. WO 98/32845 teach antibodies comprising one or more defined CDRs with the remaining CDRs being unknown. Thus, the specification coupled with the state of the art with respect antibodies does, indeed, provide sufficient description of the structure of the antibodies of the claimed invention to reasonably convey to one of skill in the art that Applicants were in possession of the antibodies of the claimed invention.

Second, methods for identifying antibodies that immunospecifically bind to a human TANGO 268 antigen are described in the instant specification and were well-known as of the effective filing date of the instant application. See, page 104, lines 18-29 and page 51, line 1 to page 56, line 22 of the instant specification of the application, and Chapter 14 of Harlow et al., eds, 1988, Antibodies A Laboratory Manual, Cold Spring Harbor, New York (Exhibit J). Thus, contrary to the Examiner's contention, Applicants respectfully assert that the specification coupled with the state of the art with respect to antibodies would reasonably convey to one of skill in the art that Applicants were in possession of an antibody comprising a CDR having an amino acid sequence of a CDR encoded by the cDNA insert of the plasmid deposited with the ATCC® as patent deposit Number PTA-2442, wherein the antibody immunospecifically binds to a human TANGO 268 antigen, as of the effective filing date of the instant application.

In view of the foregoing, Applicants respectfully request that the rejections under 35 U.S.C. § 112, first paragraph, for lack of written description be withdrawn.

#### **B. THE CLAIMED INVENTION IS ENABLED**

Claims 132-264 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make

and/or use the invention. For the reasons detailed below, respectfully assert that the rejections under 35 U.S.C. § 112, first paragraph, for lack of enablement cannot stand and should be withdrawn.

The Examiner contends that the an affidavit or declaration by Applicants, or a statement by an attorney of record is required to assure that the deposited material recited in claims 132-264 will be irreovocably and without restriction released to the public upon the issuance of a patent. Applicants respectfully direct the Examiner's attention to the attached Statement of Attorneys Applicants Regarding the Permanence and Availability of Deposited Microorganisms ("Statement"; Exhibit K), which attests to the deposit of microorganisms under the provisions of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, in compliance with the criteria set forth by 37 C.F.R. §§ 1.801-1.809 regarding the availability and permanence of deposits. Accordingly, the Statement obviates the Examiner's rejection based on the availability of the deposited material recited in claims 132-264.

The Examiner contends that the specification provides insufficient guidance regarding the antigen recognized by the antibodies of the claimed invention. The Examiner also contends that the scope of the claims is not commensurate with the enablement provided by the specification regarding the extremely large number of combinations of CDR domains that must be tested in order to identify antibodies with specific binding to a TANGO 268 antigen. The Examiner points to Janeway et al., Immunobiology 4<sup>th</sup> Edition, Garland Press, London, 1999 to support the contention that the juxtaposition of the VH CDRs and VL CDRs form the antigen binding site of an antibody. The Examiner relying on Janeway et al., Immunobiology 4<sup>th</sup> Edition, Garland Press, London, 1999 contends that the specification fails to provide sufficient disclosure regarding the antibodies recited in claims 132-230 and 233-264 which encompass up to five undefined CDR regions, which antibodies immunospecifically bind to a TANGO 268 antigen. Further, the Examiner contends that it is unclear how one would identify a purified antibody that competes with an scFv antibody encoded by the cDNA insert of the plasmid deposited with the ATCC® as patent deposit Number PTA-2442 for binding to a TANGO 268 antigen, as recited in claims 254 and 255.

As discussed above, claims 137, 139, 141, 143, 145, 147, 149, 151, 153, 156, 158, 160, 166, 167, 170, 172, 174, 179, 182, 184, 186, 190, 193, 195, 197, 202, 204, 206, 209, 214, 217, 219, 221, 225, 228, 230, 232, 236, 239, 241, 243, 244, 253 and 255 have been

canceled without prejudice to Applicants' right to pursue the subject matter of the canceled claims in related applications. Further, claims 132, 140, 144, 148, 152, 159, 245-247, 254, and 256-264 have been amended to clarify what Applicants regard as the claimed invention.

The test for enablement is whether one reasonably skilled in the art could make or use the invention, without undue experimentation from the disclosure in the patent specification coupled with information known in the art at the time the patent application was filed. *U.S. v. Telelectronics, Inc.* 857 F. 2d 778, 8 U.S.P.Q. 2d 1217 (Fed. Cir. 1988). Enablement is not precluded even if some experimentation is necessary. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F. 2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). The Court of Appeals for the Federal Circuit has determined that experimentation, though laborious, is not undue experimentation where the specification provides a reasonable amount of guidance. *In re Wands*, 858 F. 2d 731 (Fed. Cir. 1988). In the present instance, the specification provides one of ordinary skill in the art with sufficient guidance to meet the requirements of Section 112. Therefore, as explained below, the claimed invention is enabled within the meaning of Section 112.

Applicants respectfully assert that the specification coupled with information well-known as of the effective filing date of the instant application provides sufficient guidance to enable one of skill in the art to practice the claimed invention without undue experimentation. First, as discussed above, Applicants have amended independent claims 132 and 254 (and claims dependent thereof) to recite substantially purified antibodies that immunospecifically bind to a human TANGO 268 antigen. The specification at, *e.g.*, page 51, line 1 to page 56, line 22 teaches that the scFv entitled A10, deposited with the ATCC® as patent deposit Number PTA-2442, immunospecifically binds to a human TANGO 268 antigen. Thus, the amendment to claim 254 obviates the Examiner's rejection of claim 254 under 35 U.S.C. § 112, first paragraph, for lack of enablement. Further, the amendment to claim 132 (and claims dependent therefrom) clarifies that the antibodies of the recited in presently pending claims 132-136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 155, 157, 159, 161-165, 168, 169, 171, 173, 175-178, 180, 181, 183, 185, 187, 188, 189, 191, 192, 194, 196, 198-201, 203, 205, 207, 208, 210-213, 215, 216, 218, 220, 222-224, 226, 227, 229, 231, 233-235, 237, 238, 240, 242, 245-251 and 256-264 immunospecifically bind to human TANGO 268.

Second, Applicants respectfully direct the Examiner's attention to the Declaration of Dr. Davinder Gill Under 37 C.F.R. § 1.132 (the "Gill Declaration"; attached hereto as Exhibit

F). As discussed in the Gill Declaration and as taught in International Publication No. WO 98/32845, methods for generating antibodies comprising a minimum of one defined CDR and up to five undefined CDRs were well-known to one of skill in the art as of the effective filing date of the instant application (see paragraph 6 of the Gill Declaration). Moreover, as discussed in the Gill Declaration, methods for identifying antibodies comprising a minimum of one defined CDR and up to five undefined CDRs which antibodies immunospecifically bind to a human TANGO 268 were well-known to one of skill in the art as of the effective filing date of the instant application (see paragraph 7 of the Gill Declaration). Further, as discussed in the Gill Declaration, a post-filing date publication, *i.e.*, Soderlind et al., 2000, *Nature Biotechnology* 18: 852-856, demonstrates the successful selection of antibodies comprising unknown CDRs which immunospecifically bind to a particular antigen (see paragraph 7 of the Gill Declaration). Thus, routine methods for generating and identifying antibodies comprising a CDR having an amino acid sequence of a CDR encoded by the ATCC® as patent deposit Number PTA-2442, wherein said antibodies immunospecifically bind to a human TANGO 268 antigen, were well-known to one of skill in the art as of the effective filing date. Accordingly, the specification coupled with information well-known in the art as of the effective filing date of the instant application fully enables one of skill in the art to practice the claimed invention without undue experimentation.

In view of the foregoing, Applicants respectfully request that the rejections under 35 U.S.C. § 112, first paragraph, for lack of enablement be withdrawn.

### CONCLUSION

Applicants respectfully request entry and consideration of the foregoing amendments and remarks. Applicants believe that all of the present claims meet all the requirements for patentability. Withdrawal of all rejections and reconsideration of the amended claims are requested. An allowance is earnestly sought.

If any issues remain, the Examiner is requested to telephone the undersigned at (212) 790-6431.

Respectfully submitted,

Date June 18, 2002

Laura A. Coruzzi 30,742  
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By:

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